IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION	Civil Action No. 01-1652 (JAG) (Consolidated Cases)
This Document Relates To:	
All Direct Purchaser Actions	MDL Docket No. 1419

SPECIAL MASTER'S REPORT AND RECOMMENDATION ON DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AS TO THE UPSHER AND ESI SETTLEMENTS AND DIRECT PURCHASER PLAINTIFFS' PARTIAL MOTIONS FOR SUMMARY JUDGMENT AS TO THE APPLICABLE FRAMEWORK FOR ANALYSIS OF EXCLUSION PAYMENTS AND THE EXCLUSIONARY SCOPE OF THE '743 PATENT

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I. INTRODUCTION

This consolidated antitrust action has been transferred to the District of New Jersey by the Judicial Panel on Multidistrict Litigation pursuant to 28 U.S.C. § 1407. Pursuant to Rule 53 of the Federal Rules of Civil Procedure[1] and by consent of all parties in the above-captioned action, I have been appointed by order of this Court, dated April 12, 2006, to preside as a Special Master to review and decide all currently pending and future motions directed to Judge Joseph A. Greenaway, Jr. and Magistrate Judge Madeline Cox Arleo including, but not limited to discovery disputes, class certification and summary judgment (the "Appointment Order") (Doc. No. 316).

[1] **(a) Appointment.**

(1) Unless a statute provides otherwise, a court may appoint a master only to:

(A) perform duties consented to by the parties;

* * *

(C) address pretrial and post-trial matters that cannot be addressed effectively and timely by an available district judge or magistrate judge of the district.

The Appointment Order provides that the decision of the Special Master on any matter before the Special Master will conclusively resolve that matter unless an appropriate objection is filed pursuant to Fed. R. Civ. P. 53(g).

This Report and Recommendation addresses the following Motions: (1) Motion of Defendants Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher) (collectively, "Defendants") for Summary Judgment as to All Claims Brought By Direct Purchaser Plaintiffs ("DP Plaintiffs" or "DPPs") Related to the Upsher Settlement ("Upsher Motion.");[2] (2) Defendants' Motion for Summary Judgment as to All Claims Brought By DPPs Related to the ESI Settlement ("ESI Motion");[3] (3) DPPs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments ("Framework

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Fed. R. Civ. P. 53(a).

[2] In support of the Upsher Motion, Defendants' submitted an opening Memorandum of Law (accompanied by 125 exhibits attached to the 7/25/08 O'Shaughnessy Decl.) ("Upsher Mem."), a Statement of Undisputed Facts ("Def. Upsher Facts"), a Reply Memorandum of Law in support of the Uphser and ESI Motions (accompanied by 40 exhibits attached to the 10/3/08 O'Shaughnessy Decl.) ("Upsher/ESI Reply"), a Reply to DPPs' Statement of Disputed Facts in Opposition to the Upsher Settlement ("Def. Upsher Reply Facts"), and a 10/21/2008 letter brief regarding a recent Federal Circuit Court of Appeals decision. In response, DPPs submitted a consolidated Memorandum of Law in opposition to the Upsher Motion and the ESI Motion (accompanied by 158 exhibits attached to the 9/5/2008 Refsin Decl.) ("Upsher/ESI Opp."), a Statement of Disputed Facts in Opposition to the Upsher Motion ("DPP Upsher Facts"), and a 10/31/2008 letter brief.

[3] In support of the ESI Motion, Defendants submitted an opening Memorandum of Law (accompanied by 46 exhibits attached to the 7/3/08 O'Shaughnessy Decl.) ("ESI Mem."), a Statement of Undisputed Facts ("Def. ESI Facts"), the Upsher/ESI Reply, a Reply to DPPs' Statement of Disputed Facts in Opposition to the ESI Motion ("Def. ESI Reply Facts") and the above-referenced 10/21/2008 letter brief. In response, DPPs submitted the Upsher/ESI Opp., a Statement of Disputed Facts in Opposition to the ESI Motion ("DPP ESI Facts"), and the above-referenced 10/31/2008 letter brief.

Motion");[4] and (4) DPPs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent ('743 Motion").[5]

After consideration of the parties' voluminous submissions in support of and in opposition to the above-referenced Motions,[6] as well as the oral argument of counsel presented on December 10, 2008, I conclude, based on the following analysis, that: (1) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the Upsher Settlement is granted; (2) Defendants' Motion Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the ESI Settlement is granted; (3) DP Plaintiffs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments is denied; and (4) DP Plaintiffs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent is denied.

II. BACKGROUND

This action involves the drug K-Dur 20, a potassium chloride supplement manufactured by Schering. Schering entered into separate agreements with Upsher and ESI Lederle ("ESI") settling patent litigation that Schering had initiated after Upsher and ESI sought approval from the Food and Drug Administration ("FDA") for their generic versions of K-Dur. The gravamen of DP Plaintiffs' Complaint is that Schering's settlements with Upsher and ESI were collusive, anticompetitive agreements that had the effect and purpose of preventing and delaying the entry

[4] In support of the Framework Motion, DPPs submitted an opening Memorandum of Law (accompanied by four exhibits) ("Framework Mem."), a Statement of Undisputed Facts ("DPP Framework Facts"), and a Reply Brief (accompanied by two appendices with a total of two exhibits) ("Framework Reply"). In response, Defendants submitted a Brief in Opposition to the Framework Motion (accompanied by 14 exhibits attached to the 9/5/08 O'Shaughnessy Decl.) ("Framework Opp.") and a Counterstatement of Material Facts ("Def. Framework Facts").

[5] In support of the '743 Motion, DPPs submitted an opening Memorandum of Law (accompanied by 15 exhibits ("'743 Mem."), a Statement of Undisputed Facts ("DPP '743 Facts"), and a Reply Brief (accompanied by two exhibits) ("'743 Reply"). In response, Defendants' submitted a Brief in Opposition to the '743 Motion accompanied by seven exhibits ("'743 Opp."), and a Counterstatement of Material Facts a ("Def. '743 Facts").

of generic substitutes for K-Dur and allowing Schering to maintain a monopoly in the extended release potassium chloride supplement market. (DPP Am. Compl., ¶ 1). *See also In re K-Dur Antitrust Litigation,* 338 F. Supp. 2d 517, 522, 526 (D.N.J. 2004). Plaintiffs allege that but for payments made by Schering to Upsher and ESI under the agreements, Upsher and ESI would have settled on different terms and their generic products would have entered the market earlier than was permitted under the settlements. (DPP Am. Compl. at ¶¶ 1, 109). *See also In re K-Dur,* 338 F. Supp. 2d at 526.

As is evident from the discussion to follow, this case involves complex legal and factual issues at the intersection of patent and antitrust law. Accordingly, before analyzing the parties' motions, it is necessary to outline the regulatory, factual and procedural contexts in which the issues presented arise.

A. Statutory and Regulatory Framework

A pharmaceutical company must obtain FDA approval to market a prescription drug. 21 U.S.C. § 355(a). In order to obtain approval for a pioneer drug, a company must submit a New Drug Application ("NDA"), which details all safety and efficacy studies, the components in the drug, the methods used in "the manufacture, process and packaging" of the drug, and any patents issued on the composition or methods of using the drug. *Id.* at § 355(b)(1). The FDA publishes the patent information in the "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." *See* FDA Electronic Orange Book, http://www.fda.gov/cder/ob/.

Prior to 1984, a generic drug company also had to undertake its own costly studies regarding the efficacy and safety of a drug, even if the drug was a bioequivalent of a brand name

[6] The parties' summary judgment submissions include more than 400 pages of briefs and factual statements and a total of more than 400 exhibits.

drug already on the market. *See Schering-Plough Corp. v. Fed. Trade Comm'n,* 402 F.3d 1056, 1058-59 n.2 (11th Cir. 2005), *cert. denied,* 126 S.Ct. 2929 (2006) (*"Schering")* (explaining the NDA process and indicating its potential cost). The generic was then required to file its own NDA for its version of the drug. The generic company could not begin testing the drug until after the patent life on the brand-name drug expired, since before that time the pioneer company could sue the generic for patent infringement. *See* 35 U.S.C. § 271 (2000) (stating that making or using a patented compound is an act of infringement).

In 1984, Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified at various sections of titles 21 and 35 of the United States Code). Among its key provisions, the Hatch-Waxman Act: (1) created the Abbreviated New Drug Application ("ANDA"), which allows a generic drug applicant to piggyback on safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); (2) modified the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and (3) allowed the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process. *See generally* 35 U.S.C. § 156.

Under the The Hatch-Waxman Act, the pioneer drug maker still files a NDA with full-scale safety and efficacy studies and lists the patents that generics might infringe in the future. 21 U.S.C. § 355(b)(1) (enumerating NDA provisions). However, a generic company may file an ANDA, which requires the generic to prove that the new drug is the bioequivalent of a brand-name drug on the market, but does not require the time-consuming studies required for a NDA. *Id.* at § 355(j)(2)(A) (listing the ANDA provisions). *See also Schering,* 402 F.3d at 1058-59 n.2

(generics can use a "truncated" process, "so long as the generic manufacturer proves that its drug is a bio-equivalent to the already-approved brand name/pioneer drug"); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes ("Hovenkamp"),* 87 Minn. L. Rev. 1719, 1753 (2003) (listing ANDA provisions and noting that generic must be bioequivalent of pioneer drug). Further, the generic may begin testing before the pioneer's patent expires. 35 U.S.C. § 271(e)(1).

Under the Hatch-Waxman Act, an ANDA filer must make one of the following certifications: (1) that the "patent information has not been filed" on the generic's brand-name equivalent (a paragraph I certification); (2) that a "patent [on the branded drug] has expired" (a paragraph II certification); (3) that a brand-name patent exists, "the date on which such patent will expire," with a promise not to market until that date (a paragraph III certification); or (4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted" (a paragraph IV certification). (a paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added).

If the ANDA filer makes a paragraph IV certification, it must consult the Orange Book and provide notification to each NDA or patent owner impacted by the ANDA certification "not later than [twenty] days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed." *Id.* at § 355(j)(2)(B)(ii)(I). The filing of an ANDA with a paragraph IV certification allows the patent holders to sue, as it is considered a technical act of infringement, even though the generic has not yet begun marketing its version of the drug. *See* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs,* 30 J. Corp. L. 309, 317 (2005) (noting that paragraph IV certification is a technical act of infringement because the generic intends to

market and infringe the patent). The patent owners then have 45 days to bring an infringement suit against the generic. If the affected patent owners do not file suit, the FDA can approve the ANDA without delay. 21 U.S.C. § 355(j)(5)(B)(iii). However, if an affected patent owner brings an infringement suit, approval of the application is automatically stayed for thirty months, or until a district court issues a final decision concluding that the patent has not been infringed or is otherwise invalid. *Id.*

In order to give generic drug makers an incentive to incur the expense and risk of a potential infringement suit by the patent holder, the ANDA procedures give the first ANDA filer a 180-day exclusivity period. *Id.* at 355(j)(5)(B)(iv). During this exclusivity period, the FDA cannot approve any other generic manufacturer's ANDA until 180 days after the earlier of (1) the date of the first ANDA filer's commercial marketing of its generic drug; or (2) the date of a "court [decision ruling] that the patent is invalid or not infringed."[7] *Id* at 355(j)(5)(B)(iii)(I).

B. Factual and Procedural Background[8]

1. The Parties

The DP Plaintiff Class, represented by lead Plaintiff Louisiana Wholesale Drug, is essentially comprised of all persons or entities who purchased K-Dur 20 directly from Schering

[7] Prior to 2000, this was calculated from a "final judgment from which no appeal can be or has been taken." 21 C.F.R. § 314.107(e)(1) (1999). Now, a district court decision is sufficient. *Mylan Pharms., Inc. v. Shalala,* 81 F. Supp. 2d. 30 (D.D.C. 2000). Also, prior to 1998, FDA regulations had required that ANDA filers would not get the 180-day exclusivity unless they had successfully defended the patent infringement suit. *See* 59 Fed. Reg. 50,338,367 (Oct. 3, 1994). The "successful defense" requirement was subsequently found to be unreasonable, *Mova Pharms. Corp. v. Shalala,* 140 F.3d 1060, 1069-70 (D.D.C. 1998), and the FDA dropped the requirement in 1998. *See* 63 Fed. Reg. 59,710,711 (Nov. 5, 1998).

[8] The facts pertinent to the current motions are drawn primarily from the parties' pleadings and their respective statements filed pursuant to Local Rule 56.1 Unless otherwise indicated, the facts set forth below are not in dispute.

during the period November 20, 1998, through September 1, 2001.[9] The Class includes wholesalers, hospitals, health maintenance organizations and retail drug store chains.

Schering is a New Jersey corporation engaged in the discovery, development and marketing of, *inter alia,* brand name and generic drugs. Upsher is a Minnesota corporation engaged in the discovery, development and marketing of brand name and generic drugs. Former Defendant Wyeth Laboratories ("Wyeth"), formerly known as American Home Products, Inc. ("AHP"), is a Delaware corporation engaged in the development, manufacturing and marketing of, *inter alia,* brand name and generic drugs. Former Defendant ESI is a business unit of Wyeth that engages in the research, manufacture and sale of generic drugs.[10]

2. K-Dur and the '743 Patent

During the time period relevant to the DP Plaintiffs' claims, Schering marketed a potassium chloride supplement under the brand name K-Dur. (DPP Upsher Facts, ¶ 1).[11] K-Dur is used to treat potassium deficiencies such as those that often arise from the treatment of high

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[9] On April 14, 2008, I issued a Report and Recommendation (the "April 14 R&R") recommending that DP Plaintiffs' Motion for Class Certification be granted and the following Class certified:

> All persons or entities who have purchased K-Dur 20 directly from Schering at any time during the period November 20, 1998, through September 1, 2001.
>
> Excluded from the proposed class shall be:
>
> Defendants and their officers, directors, management and employees, subsidiaries and affiliates, as well as federal government entities. Also excluded are persons or entities who have not purchased generic versions of K-Dur 20 after the introduction of generic versions of K-Dur 20.

(April 14 R&R, Doc. No. 636). On December 30, 2008, Judge Greenaway overruled the objections of Defendants and DP Plaintiffs to the April 14 R&R and adopted the R&R as the opinion of the Court. (Dec. 30, 2008 Order, Doc. No. 731).

[10] On January 24, 2005, Judge Greenaway granted final approval of a settlement between DP Plaintiffs and Wyeth. (Jan. 24, 2005 Order, Doc. No. 226). As part of the settlement, DP Plaintiffs agreed to the release and dismissal with prejudice of all claims against Wyeth and its related entities, including ESI. (DPP/Wyeth Settlement Agreement, Doc. 170-3).

[11] In the interest of brevity, the record citations herein regarding the factual background refer to the parties' statements filed pursuant to Local Rule 56.1 and, unless necessary, do not separately identify each exhibit cited by the parties in their statements of fact. In addition, because the DPP Upsher Facts and the DPP ESI Facts restate each

blood pressure with diuretic products. (DPP '743 Facts, ¶ 1; Def. '743 Facts, ¶ 1). Although the active ingredient in K-Dur – potassium chloride – is not patented, K-Dur is covered by a formulation patent, No. 4,863,743 (the "'743 Patent"), owned by Key Pharmaceuticals, Inc. ("Key"), a division of Schering. (Schering Ans. to DPP Am. Compl., ¶ 23-24). The '743 Patent, which claims a controlled-release dispersible potassium chloride tablet, was issued on September 5, 1989 and expired on September 5, 2006. (Schering Ans. to DPP Am. Compl. at ¶ 24; DPP Uphser Facts, ¶ 9).

The '743 Patent has 12 claims, all of which depend on or incorporate Claim 1. (DPP Upsher Facts, ¶ 49; DPP '743 Facts, ¶ 12; Def. '743 Facts, ¶ 12). Claim 1 of the '743 Patent states:

> A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride, comprising;
>
> a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 64% to about 86.5% by weight based on the total weight of the dosage unit;
>
> a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and said ethylcellulose has a viscosity greater than 40 cp.

('743 Mem., Ex. 1 ('743 Patent) at Col. 8, line 18-Col. 10, line 21). With regard to tablets, the '743 Patent specification states, *inter alia,* "[t]he useful ethylcellulose designations are 7 and higher, corresponding to a viscosity of at least 6 cp, preferably more than 40 cp (designations 45 or higher) for crystals to be compressed into tablets." (*Id.* at Col. 4, lines 63-66).

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paragraph of Defendants' Upsher Facts and ESI Facts, it is not necessary to cite separately to Defendants' Upsher Facts and ESI Facts.

3. Development and Prosecution of the '743 Patent

The sustained release potassium chloride tablet claimed in the '743 Patent was developed at Key by Charles Hsiao and Chi-Tze Chou using a technique called "microencapsulation." (DPP Upsher Facts, ¶ 4). Microencapsulation is a process in which small particles of a drug are coated to give them sustained release properties. (DPP Upsher Facts, ¶ 5). Tableting exposes the coated microcapsules to compression forces as the individual crystals are compressed into a tablet. (*Id.*). Dr. Hsiao and Ms. Chou used a coating consisting of insoluble ethylcellulose ("EC") with a viscosity of greater than 40 centipoise ("cp") and either hydroxypropylcellulose ("HPC") or polyethylene glycol ("PEG"). (DPP Upsher Facts , ¶ 8). Viscosity is a property of fluid that refers to its resistance to flow. (DPP '743 Facts, ¶ 14; Def. '743 Facts, ¶ 14). The addition of HPC or PEG permits the potassium chloride to leach out through the EC coating. (*Id.*).

The '743 Patent issued from patent application No. 830,981 (the "'981 application"), filed February 19, 1986. (Schering Ans. to DPP Am. Complaint, ¶ 29). The '981 application was a continuation-in-part of application No. 702,714 (the "'714 application"), filed February 19, 1985. (DPP '743 Facts, ¶ 19; Def. '743 Facts, ¶ 19). As originally filed, Claim 1 of the '981 application did not contain any limitation on the viscosity grade of the ethylcellulose used in the coating material. (DPP Upsher Facts, ¶ 50). In addition, as originally filed, Claim 1 described a "dosage unit" for oral administration of potassium chloride, and was not limited to a tablet dosage form. (*Id.*).

On August 31, 1988, the Patent and Trademark Office ("PTO") rejected the then-pending claims of the '981 application based on Patent No. 4,555,399 (the "'399 Patent") and other prior art. (DPP '743 Facts, ¶ 28; Def. '743 Facts, ¶ 28). The '399 Patent had previously been granted to Dr. Hsaio for a controlled release tablet aspirin tablet in which aspirin crystals are coated with

EC and HPC and compressed into tablet form. (DPP Upsher Facts, ¶ 51; DPP '743 Facts, ¶ 23; Def. '743 Facts, 23). Example 1 of the '399 Patent describes the use of Ethocel N-10 (Dow), an EC with a viscosity of 9-11 cp. (Upsher/ESI Opp., Ex. 167 ('399 Patent) at Col. 3, line 8; '743 Mem., Ex. 2 (Feb. 27, 1989 Amendment) at 5. However, DP Plaintiffs dispute that the '399 Patent limited the claimed invention in any way to 9-11 cp ethylcellulose. (DPP Upsher Facts, ¶ 51).

After the PTO's August 31, 1988 rejection, Key filed a response that included an amendment to Claim 1 and arguments in support of patentability. (DPP Upsher Facts, ¶ 52). Key amended Claim 1 by specifying that the invention was a "tablet" and by adding the phrase "said ethylcellulose has a viscosity greater than 40 cp" at the end of Claim 1. (DPP Upsher Facts, ¶ 52-53; '743 Mem., Ex. 2 (Feb. 27, 1989 Amendment) at 1-2). In its remarks accompanying the amendment, Key stated, *inter alia,* that "the claims have been amended to more precisely define the claimed invention," and argued that a review of the prior art '399 Patent would not lead one skilled in the art to use EC with a viscosity of greater than 40 cp to make a sustained release potassium chloride tablet as claimed in the '981 application. (DPP Upsher Facts, ¶ 54). Key further stated that the prior art '399 Patent disclosed only EC with a viscosity of 9-11 cp. (*Id.*). On March 31, 1989, the Patent Examiner granted Key the '743 Patent. (DPP Upsher Facts, ¶ 55).

4. The Upsher Patent Litigation

On August 8, 1995, Upsher filed an ANDA with the FDA seeking permission to sell a generic version of K-Dur. (DPP Upsher Facts, ¶ 12). Upsher's generic product, Klor-Con© M20, was a microencapsulated, controlled release 20mEq potassium chloride tablet. (*Id.* at 13). Upsher certified to the FDA that its product was bioequivalent to K-Dur and stated that its product was "the same as the reference drug, K-DUR." (*Id.* at 15-16). In its November 3, 1995

paragraph IV Certification Notice to Schering, Upsher claimed that its generic drug would not infringe the '743 Patent. (DPP Upsher Facts, ¶ 17). Specifically, Upsher asserted that its product did not infringe Key's product because: (1) "the viscosity of ethyl cellulose employed in KLOR-CON© M is outside the range limited by claim 1 of the '743 patent;" and (2) "[t]he KLOR-CON© M product does not contain hydroxypropylcellulose." (Upsher Mem., Ex. 17 (Nov. 13, 1995 Patent Certification Notice) at 8-9).[12] Uphser's product used sorbitan monooleate ("SMO"). (DPP Upsher Facts, ¶ 18). Upsher disputes "any implication that it used SMO in place of HPC or PEG," and disputes that the SMO used in Upsher's product was present in an amount corresponding to the claimed amount of HPC or PEG required by the claims of the '743 Patent. (*Id.*). In its Patent Certification Notice, Upsher also asserted that because, in its amendment of Claim 1, Key inserted a limitation of viscosity for EC of greater than 40 cp, prosecution history estoppel precluded Key from "assert[ing] the doctrine of equivalents in alleging that the KLOR-CON© M product infringes its claims." (Upsher Mem., Ex. 17 (Nov. 13, 1995 Patent Certification Notice) at 9-13).

On December 15, 1995, Key filed an action in the United States District Court for the District of New Jersey against Upsher alleging "willful and deliberate" infringement of the '743 Patent. (DPP Upsher Facts, ¶ 19). The case was assigned to Judge Walls. (*Id.* at ¶ 23). Key's action was timely commenced within the 45-day period specified in the Hatch-Waxman Act. (*Id.* at ¶ 19). Upsher answered Key's complaint, denying infringement and alleging declaratory judgment counterclaims for patent invalidity, non-infringement and unenforceability. (*Id.* at ¶ 23).

[12] Upsher's Patent Certification Notice also stated that "the KLOR-CON© M product does not contain magnesium stearate of polyvinylpyrolidone." (*Id.* at 9).

Discovery in the case included the exchange of tens of thousands of pages of documents and depositions of the inventors and patent attorneys from Key and Schering, as well as of the Upsher technical people and consultants who developed the Upsher formulation. (*Id.* at ¶ 24). Schering retained as an expert, Dr. Gilbert S. Banker, dean of the University of Iowa College of Pharmacy. (*Id.* at ¶ 25). Key retained as its technical expert, Dr. Christopher Rhodes, a co-editor with Dr. Banker of the textbook, *Modern Pharmaceutics*. (*Id.* at ¶ 27). Drs. Banker and Rhodes each submitted expert reports, and both were deposed for multiple days. (*Id.* at ¶ 28, 30). Dr. Banker opined that the '743 Patent was valid and infringed by Upsher's product; Dr. Rhodes opined that the '743 Patent was invalid and that the Upsher formulation was not equivalent to the claims of the '743 Patent. (*Id.* at 29).

On February 6, 1997, Upsher moved for summary judgment on the issue of non-infringement. (*Id.* at ¶ 31). Upsher argued that Key was barred by prosecution history estoppel from claiming that the Upsher product was equivalent to the '743 Patent, and that no factual equivalency existed between its generic product and the claims of the '743 Patent. (*Id.* at ¶ 31). In opposition to the Motion, Key argued that it was not barred by prosecution history estoppel from asserting equivalency, and that factual disputes existed regarding whether Upsher's formulation was equivalent to the '743 Patent. (*Id.* at ¶ 32). Key separately moved for summary judgment on Upsher's affirmative defenses that the '743 Patent was unenforceable based on inequitable conduct before the PTO. (*Id.* at 34). Upsher opposed Key's motion on the ground that fact disputes concerning the alleged inequitable conduct precluded summary judgment. (*Id.* at ¶ 35).

On June 17, 1997, Judge Walls held a hearing on certain motions, including Upsher's motion for summary judgment. ("743 Mem., Ex. 9). Trial in the *Key v. Upsher* matter was scheduled to being on June 18, 1997.

5. The Upsher Settlement

Upsher initiated contact with Schering to discuss settlement of the patent litigation. (DPP Upsher Facts, ¶ 68). The first settlement meeting took place on May 21, 1997, with subsequent discussions between the parties occurring on May 28, June 3, and June 12, and June 16, 1997. (DPP Upsher Facts, ¶¶ 197, 199, 205; Def. Upsher Reply Facts, ¶¶ 197, 199, 205). In the early morning hours of June 18, 1997, the parties signed and finalized an agreement, dated June 17, 1997 (the "June 17 Agreement"), "as to the terms under which [Upsher and Schering, on behalf of itself and Key] will settle the [*Key v. Upsher*] action and will enter into a transaction licensing rights to certain Upsher-Smith products to an affiliate of Schering." (DPP Upsher Facts, ¶ 208; Def. Upsher Reply Facts, ¶ 208; Upsher Mem., Ex. 61 (June 17, 1997 letter from Raman Kapur to Ian Troup) at p. 1).

The terms of the June 17 Agreement pertinent to the instant Motions provided that: (1) Upsher would not market its Klor-Con© M20 product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001; (2) effective September 1, 2001, Schering would grant Upsher a non-royalty bearing non-exclusive license to market its Klor-Con© M20 and Klor-Con© M10 product in the United States; (3) Upsher would grant Schering licenses to Upsher's Niacor-SR© and five other Upsher products;[13] and (4) "[i]n consideration for the licenses, rights and obligations described in paragraphs 1 through 10" of the agreement, Schering would pay to Upsher a total of $60 million, comprised of $28 million

[13] The five other Upsher products were KLOR CON© 8, KLOR CON© 10, KLOR CON© M20, PREVALITE©, and Pentoxifylline. (Upsher Mem., Ex. 61 (June 17 Agreement) at ¶¶ 7-10).

payable upon approval of the agreement by Schering's Board of Directors, $20 million on the first anniversary of the approval date, and $12 million on the second anniversary of the approval date.[14] (Upsher Mem., Ex. 61 (June 17 Agreement) at ¶¶ 3, 7-11).

The parties dispute the facts regarding the *bona fides* of the Niacor-SR© license deal and the reasons it was included in the June 17 Agreement. DP Plaintiffs contend that the deal was effectively a sham and that all or part of the $60 million paid to Upsher by Schering under the Agreement was really for Upsher's agreement to delay the entry of its generic K-Dur. (Uphser Opp., pp. 37-66; DPP Upsher Facts, ¶¶ 72-106, 192-277). Schering contends that the Niacor-SR© license was a separately valued deal, that the $60 million was a good faith payment for rights Schering believed – in its business judgment at the time – were worth $60 million, and that the deal was included in the June 17 Agreement only after Schering was satisfied that the deal stood on its own merit. (Upsher Mem., pp. 41-66; Upsher/ESI Reply, pp. 18-27; DPP Upsher Fact, ¶¶ 72-106; 192-277).

6. The ESI Patent Litigation and Settlement

On December 29, 1995, ESI sought FDA approval to market a generic version of K-Dur. (DPP ESI Facts, p 3; Schering Ans. to DPP Am. Complaint, ¶ 78). ESI's product was a sustained release tablet for oral administration of potassium chloride. It used the ingredients potassium chloride, EC and HPC in amounts within the ranges specified by Claim 1 of the '743 Patent. (DPP ESI Facts, ¶ 4). ESI submitted a Paragraph IV Certification and notified Schering of its Paragraph IV Certification and ANDA filing. (Schering Ans. to DPP Am. Complaint, ¶ 78).

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[14] The Agreement also provided for milestone and royalty payments contingent upon Schering's sales of Niacor-SR©. Subsequent to the June 17 Agreement, Schering decided not to pursue the Niacor-SR© opportunity, and

On February 16, 1996, Schering (through Key) sued ESI in the United States District Court for the Eastern District of Pennsylvania, alleging that ESI's generic product infringed the '743 Patent. (DPP ESI Facts, ¶ 5; Schering Ans. to DPP Am. Compl., ¶ 80). ESI argued that its product did not literally infringe the "743 Patent because ESI's product did not have a "coating material with different ingredients" as required by the '743 Patent. (ESI Opp., Ex. 145 (ESI Reply Mem. in Support of Defendant's Mot. for a Markman Ruling on Patent Claim Construction and/Or for Partial Summary Judgment of No Literal Infringement and Response to Plaintiff's Cross Motion), at p. 2). ESI stated that its "tablets are made by a completely different technology which produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient." (*Id.* at p. 13).

In the Fall of 1996, Schering and ESI agreed to engage in court-supervised mediation. (DPP ESI Facts, ¶ 7). The mediation session was suggested by the presiding District Judge, the Hon. Jan DuBois, to whom the case was assigned. (*Id.*). U.S. Magistrate Judge Thomas Rueter was appointed mediator. (*Id.*). During the mediation sessions, Magistrate Judge Rueter met with the parties both jointly and separately and urged them to settle. (*Id.* at ¶ 8).

In December 1997, Schering obtained information from ESI concerning problems ESI had encountered in demonstrating the bioequivalence of its generic product to K-Dur, as required for approval of ESI's ANDA. (DPP Upsher Facts, ¶ 9; Def. ESI Reply Facts, ¶ 9; ESI Mem., Ex. 13 (Dec. 15, 1997 letter, AHP 05 00175)). The information showed that the FDA had twice rejected ESI's bioequivalence studies and that ESI's most recent effort to conduct a trial showing bioequivalence had begun on December 8, 1997. (*Id.*). Also in mid-December 1997, the parties discussed a proposed settlement whereby Schering would grant ESI a royalty free license to

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Schering never marketed the drug. However, the facts regarding the reasons for Schering's decision are disputed. (DPP Am. Compl., ¶ 74; Schering Ans. to Am. Compl., ¶ 74).

market its generic Micro-K® 20 product on December 31, 2003, and ESI would grant Schering licenses for certain ESI products in exchange for a $5 million up-front royalty fee plus additional royalty fees based on sales of the products. (DPP ESI Facts, ¶¶ 10-11; Def. ESI Reply Facts, ¶¶ 10-11).

Judge DuBois held a Markman hearing on January 21 and 22, 1998. (DPP ESI Facts, ¶ 13). At the close of the January 22, 1998 session of the hearing, Judge DuBois told the parties:

> I want you to take this business decision, and it is a business decision and decide it without any more help than you're getting from Judge Rueter. I don't want you to use the adjudicatory powers of the Court.
>
> We're talking about the conciliatory services that the Court offers, and that's what I want you to use to resolve the case. I don't want to have to adjudicate either this case or the two-week long or longer trial of this case. I want you to try to do it.
>
> I think that's the best way to resolve a dispute of this kind, particularly since I think you can craft a settlement among yourselves.

(ESI Mem., Ex. 17 (Jan. 22, 1998 Tr.) at 139). At the end of the hearing, after summoning the parties to his chambers, Judge DuBois directed the parties to Magistrate Judge Rueter to try to settle the case. (DPP ESI Facts, ¶ 13; ESI Mem., Ex. 18 (Herman 10/30/01 Dep.) at 129-130).[15]

The parties had another mediation session with Magistrate Judge Rueter on Friday, January 23, 1998, which began around 5:30 p.m. and continued until 11:30 p.m. (DPP ESI Facts, ¶ 14). Participating in all or part of the session were three of Schering's counsel and one

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[15] In their Statement of Disputed Facts, DP Plaintiffs have asserted that certain of the statements cited in Defendants' Statement of Facts regarding the ESI Settlement are inadmissible hearsay. In this regard, I note that hearsay statements may be considered on summary judgment if the statements are capable of being admissible at trial. *Shelton v. Univ. of Med. & Dentistry,* 223 F.3d 220, 223 n.2 (3d Cir. 2000). Moreover, to the extent that the statements are offered not to show the truth of the matter asserted, but to demonstrate their effect on the listener, they may be admissible. *See Marks v. Marina,* 213 Fed. Appx. 147, 2007 U.S. App. LEXIS 479, at *10-11 (court properly admitted evidence offered not for its truth, but to show the effect on the listener); *Faulkner v. Super Valu Stores, Inc.,* 3 F.3d 1419, 1434 (10th Cir. 1993) ("statements offered for the effect on the listener . . . are generally not hearsay.").

Schering executive, Martin Driscoll, who participated by phone in parts of the session while attending a New Jersey Nets basketball game with his children. (*Id.*). By the time of the January 23, 1998 mediation session, the parties had agreed to a $15 million license from ESI to Schering for ESI's two generic products, and ESI had indicated that it required money to settle the case. (DPP ESI Facts, ¶ 15).

Magistrate Judge Rueter encouraged Schering to pay ESI $5 million, which he characterized as "nothing more than legal fees." (DPP ESI Facts, ¶ 16-17). During the January 23, 1998 mediation session, Magistrate Judge Rueter called Mr. Driscoll three times at the basketball game. In those calls, Magistrate Judge told Mr. Driscoll that he had been instructed by the court to reach a settlement that night and that if the parties did not reach a settlement that night, the judge wanted the parties in court at 8 a.m. the next day. (DPP ESI Fact, ¶ 16-18; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2707-11; ESI Mem., Ex. 19 (Driscoll Dep.) at 295; ESI Mem., Ex. 20 (Driscoll I.H. Tr.) at 105-7). Magistrate Judge Rueter also called John Hoffman, Schering's then in-house antitrust counsel, at home and asked Schering to pay ESI $5 million. (DPP ESI Facts, ¶ 17; ESI Mem., Ex. 10 (Hoffman Dep.) at 328, 330; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2618-20). Prior to and during the mediation, ESI requested more than $5 million to settle the case. (DPP ESI Facts, ¶ 18).

During the January 23 session, Magistrate Judge Rueter urged Mr. Driscoll to settle and emphasized that he thought the parties could reach a middle ground. (DPP ESI Facts, ¶ 18; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2707-11). Mr. Driscoll expressed his belief that ESI might have difficulty getting its product approved and discussed with Magistrate Judge Rueter a proposal under which Schering would pay ESI a certain amount if ESI's ANDA was approved by a certain date, and a lesser amount if ESI received approval at a later date. (DPP ESI Facts, ¶ 19;

ESI Mem., Ex. 19 (Driscoll Dep.) at 295-96; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2711-12). Magistrate Judge Rueter discussed the proposal with Mr. Hoffman, and characterized it as a "bet." (DPP ESI Facts, ¶ 21; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2620). Regarding Schering's doubt that ESI would receive FDA approval, Magistrate Judge Rueter told Mr. Hoffman that he should "put [his] money where [his] mouth is," and stated that if Schering's concern was correct, the proposal wouldn't cost Schering anything. (DPP ESI Facts, ¶ 22; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2621).

The January 23, 1998 mediation session concluded with the parties' agreement that Schering would pay ESI $10 million if its ANDA was approved by July 1999, with Schering's payment incrementally decreasing to $625,000 if ESI's ANDA was approved in 2002. (ESI Mem., Ex. 16 (C+B-2 002196-97) at ¶ II). The parties further agreed that Key would grant ESI a "royalty free, non-exclusive license under US Patent '743 beginning 1/1/04." (*Id.* at ¶ VI). Once the terms had been agreed to by Schering and ESI, Magistrate Judge Rueter called the participants into chambers and asked them to put the terms in writing and initial or sign them. (DPP ESI Facts, 24; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2621). Counsel for ESI prepared a handwritten document summarizing the settlement principles. (ESI Mem., Ex. 16 (C+B-2 002196-97); ESI Mem., Ex. 8 (FTC Trial Tr.) at 2488-89; 2537). The document was prepared, and was signed by representatives of Key and ESI, in the presence of Magistrate Judge Rueter. (*Id.*).

Schering and ESI signed a formal settlement agreement in June of 1998. (DPP ESI Facts, ¶ 26). Among its terms, the Agreement provided that: (1) Key would grant to ESI a non-exclusive, royalty-free license, effective January 1, 2004, to market a "Referencing Product"[16]

[16] The Agreement defined a "Referencing Product" as an ESI KCl Product, a potassium chloride product that is the subject of an ANDA or NDA that references a Key NDA, or a potassium chloride product marketed by ESI as

(ESI Mem., Ex. 24 (Settlement Agreement) at ¶ 3.1(a)(i)); (2) except with respect to a Referencing Product for which ESI was permitted to seek FDA approval pursuant to the Agreement, ESI would not, prior to the expiration of the '743 Patent: (i) apply for, sponsor or support an application for AB rating for any potassium chloride product with respect to K-Dur, or (ii) conduct, sponsor, file or support a substitutability or equivalence study of a potassium chloride product with respect to K-Dur (*id.* at ¶ 2.9); and (3) Key would pay to ESI $5 million plus an additional sum ranging from $10 million, if ESI's ANDA received FDA approval by June 30, 1999, to $625,000, if ESI received approval in 2002 (*id.* at ¶ 4.1). In the Agreement, ESI represented that it was not "developing, or currently intends or plans to develop, a potassium chloride product, other than an ESI KCI Product or other potassium chloride products" that it already made. (*Id.* at ¶ 2.8).

ESI received FDA approval for its generic K-Dur product in May 1999, and Schering paid ESI the $10 million required under Paragraph 4.1(b) of the Settlement Agreement. (DPP ESI Facts, ¶ 21). In July 2001, ESI announced that it was exiting the oral generic business altogether, and in 2002, ESI left the oral generics market. (DPP ESI Facts, ¶ 28).

7. The FTC Action

On March 30, 2001, the Federal Trade Commission ("FTC") filed a complaint against Schering, Upsher and AHP (the "FTC Action"). (DPP ESI Facts, ¶ 29). The complaint alleged, *inter alia*, that Schering's settlements with Upsher and ESI unreasonably restrained commerce and constituted unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act (the "FTC Act"). (ESI Mem., Ex. 29 (FTC Complaint) at ¶¶ 68-69). The

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equivalent to, or otherwise substitutable on a generic basis for, K-Dur. (ESI Mem., Ex. 24 (Settlement Agreement) at ¶ 1.2). An ESI KCI Product was defined as the 20 Meq extended release potassium chloride tablet described in Key's ANDA. (*Id.*).

complaint further alleged that Schering monopolized and conspired with Upsher and ESI to monopolize the potassium supplement market. (*Id.* at ¶ 70-71).

Between January and March 2002, the FTC Action was tried before an Administrative Law Judge ("ALJ"). *In re Schering-Plough*, 2002 LEXIS 40, *6 (June 27, 2002) (*"Schering-ALJ"*). The trial before the ALJ included the testimony of 41 witnesses, thousands of exhibits, and resulted in 8,629 pages of transcript. *Id.* On June 27, 2002, the ALJ issued a lengthy decision – including 431 findings of fact – ruling that the Upsher and ESI Agreements were lawful settlements of legitimate patent disputes and dismissing the FTC complaint. *Id.* at *8-9. *See also Schering,* 402 F.3d at 1061. The ALJ ruled that the theories advanced by the FTC required a presumption that the '743 Patent was not valid or that Upsher's and ESI's products did not infringe the patent. *Id.* at * 8-9. *See also Schering,* 402 F.3d at 1061. The ALJ concluded that there was "no basis in law or fact to make that presumption." *Schering-FTC,* 2002 LEXIS 40, at *9. The ALJ further concluded that a *per se* antitrust analysis of the agreements was not appropriate. *Id.* at *219-33. Rather, applying a rule of reason analysis, the ALJ emphasized the need to consider the exclusionary power of the patent at issue. *Id.* at *235-43 ("Application of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder.") Considering the exclusionary power of the '743 Patent and the inability to predict the outcome of the patent litigation, the ALJ rejected the FTC's argument that, absent Schering's payments to Upsher and ESI, the generics could have entered the market earlier. *Id.* at *242-43.

The FTC's complaint counsel appealed to the full Commission, which reversed the ALJ. *In re Schering-Plough Corp.,* 2003 FTC LEXIS 187 (Dec. 8, 2003) ("*Schering-FTC*"). Although the Commission refrained from holding that Schering's payments to Upsher and ESI

made the settlements *per se* illegal, it also declined to apply the full rule of reason analysis employed by the ALJ. *Id.* at *13, 22-27. Instead, under the analysis adopted by the Commission, once the FTC demonstrates the agreements' anticompetitive effects, the "respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible." *Id.* at *14. The Commission ruled that the FTC had demonstrated the anticompetitive effect of the agreements, and reasoned that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[17] *Id.* at *16, 52. Although the FTC ostensibly used a truncated rule of reason analysis, it essentially indicated that any settlement involving reverse payments over $2 million (an estimated cost of legal fees) would be *quid pro quo* for market delay and, thus, illegal. *Id.* at *175-76. The FTC further rejected the ALJ's conclusion that the licenses granted to Schering under the agreements were adequate consideration for the payments made by Schering, ruling instead that the payments were for delay. *Id.* at * 15-16.

The Defendants chose to appeal the FTC's decision to the Eleventh Circuit, which reversed the Commission. *Schering,* 402 F.3d 1068. The Eleventh Circuit's decision in *Schering*, and its previous decision in *Valley Drug Co. v. Geneva Pharm., Inc.,* 344 F.3d 1294 (11th Cir. 2003), *cert. denied,* 125 S.Ct. 308 (2004), are discussed, *infra.*.

[17] Although the FTC found both the Upsher and ESI Agreements unlawful, it noted the limited evidence presented regarding the ESI settlement and stated that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence." *Schering-FTC,* 2003 FTC LEXIS 187, at *166

III. DISCUSSION

A. The Parties' Motions

1. Defendants' Upsher and ESI Motions

In their Motions, Defendants contend that unless DP Plaintiffs can show either: (1) that Schering's underlying patent litigation was "objectively baseless"; (2) that the '743 Patent was procured by fraud; or (3) that terms of the settlements extended the patent's coverage beyond the Patent's potential exclusionary scope, the Upsher and ESI Settlements were lawful, even if they did include "reverse payments" to Upsher and ESI Defendants argue that under the foregoing standard, DP Plaintiffs cannot establish that Schering's patent infringement suits were baseless. According to Defendants, the patent litigation with Upsher and ESI involved disputed issues of fact and law such that Schering's claim of infringement could not possibly be deemed objectively baseless. Therefore, Defendants argue, summary judgment must be granted in their favor.

With respect to the Upsher Settlement, Defendants further argue that DP Plaintiffs cannot show that there was a "reverse payment" to Upsher and, thus, their antitrust claim must fail. In short, Defendants contend that because the $60 million Schering paid Upsher was fair value for the Niacor license – and not a net payment for delay of Uphser's generic K-Dur – there can be no antitrust violation.

In their opposition to Defendants' Upsher and ESI Motions, and in their separate Framework Motion, DP Plaintiffs contend that the legal standard proposed by Defendants is incorrect. DP Plaintiffs argue that the correct framework is either a *per se* analysis, or what they term the "FTC/Hovenkamp approach." Under the framework proposed by DP Plaintiffs, settlement agreements involving reverse payments would be subject to a rebuttable presumption of illegality, which could be overcome by proof of a pro-competitive justification for the

payment. With respect to whether the payments to Niacor were, in fact, "reverse payments," DPPs argue that the question of whether Schering paid more than fair value for the Niacor license is a "quintessential factual issue" which cannot properly be decided on summary judgment.

In addition to Defendants' two primary summary judgment arguments summarized above, Defendants contend that DP Plaintiffs have failed to present sufficient evidence of an actual anticompetitive effect on the relevant product market resulting from the settlement. According to Defendants, all generic potassium chloride supplements are interchangeable with K-Dur and, thus, must be included in the relevant market. Defendants argue that because DP Plaintiffs have failed to prove the relevant market, they cannot prove that the Upsher Settlement caused any anticompetitive effects in that market.

In response to Defendants' arguments regarding the relevant market, DP Plaintiffs contend that the anticompetitive effects of delayed generic are indisputable, have been admitted by Schering, and can be proved by direct evidence that eliminates a need for the "relevant market" analysis urged by Defendants. DP Plaintiffs further argue that if a market definition is required, the relevant market cannot simply include all potassium chloride supplements that may be therapeutic substitutes for K-Dur. Rather, they argue, the market consists of K-Dur and its AB-rated equivalents.

Finally, Defendants contend that they are entitled to summary judgment on DP Plaintiffs' damages claims on two grounds. First, Defendants argue that this is not a price-fixing case and DP Plaintiffs cannot claim "overcharge" damages because, as distributors, they were not overcharged for K-Dur but, rather, were allegedly prevented from buying additional products, *i.e.*, generic versions of K-Dur. Defendants argue that the proper measure of damages under

these circumstances is lost profits, and that DP Plaintiffs have failed to offer any evidence of such damages. Second, Defendants contend that DPPs have no claim for damages for K-Dur purchases that were subject to generic bypass.

In response, DP Plaintiffs assert that overcharge damages have long been the standard remedy for direct purchasers suing for antitrust violations. With respect to generic bypass, DPPs contend that Defendants' position is inconsistent with the only published decision on the issue, as well as with the principles underlying the antitrust laws. (Upsher Opp., p. 78 (citing *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 368-70 (D. Mass. 2004). DP Plaintiffs further argue that even if an adjustment for bypass were required, it would not affect the amount of overcharges suffered by the Plaintiff Class.

2. DPPs' '743 Motion

DP Plaintiffs' also seek partial summary judgment as to the exclusionary scope of Schering's '743 patent. This motion has two principal components. First, DPPs argue that under the doctrine of prosecution history estoppel and the "All Elements Rule," the scope of the '743 patent cannot extend to exclude Upsher's generic product. DPP's second contention is that, by its express terms, the Schering/Upsher Settlement Agreement exceeds the exclusionary scope of the '743 patent. Specifically, DPPs contend that the terms of the agreement prevent Upsher not only from selling the allegedly infringing Klor Con M, but also "any other sustained release microencapsulated potassium chloride tablet," irrespective of whether such products infringed Schering's patent.

B. Summary Judgment Standard

Motions for summary judgment are governed by Federal Rule of Civil Procedure 56. "Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the

moving party's entitlement to judgment as a matter of law." *Med Alert Ambulance, Inc. v. Atlantic Health Sys., Inc.,* No. 04-1615 (JAG), 2007 WL 2297335, *2 (D.N.J. Aug. 6, 2007) (citing *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986)).

Under Rule 56(c), the moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex,* 477 U.S. at 323 (1986) (quoting Fed. R. Civ. P. 56). "Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists." *Med Alert*, 2007 WL 2297335 at *3 (citing *Jersey Cent. Power & Light Co. v. Lacey Twp.,* 772 F.2d 1103, 1109 (3d Cir. 1985)). The party opposing the motion may not rest upon mere allegations or denials of the pleadings, "but must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 256 (1986). *See also Ridgewood Bd. of Educ. v. N.E. for M.E.*, 172 F.3d 238, 252 (3d Cir. 1999) ("Speculation and conclusory allegations do not satisfy [the nonmoving party's] duty.").

"'A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial.'" *Med Alert,* 2007 WL 2297335 at *3 (quoting *Gleason v. Norwest Mortg., Inc.,* 243 F.3d 130, 138 (3d Cir. 2001)). *See also Dasrath v. Continental Airlines, Inc.*, 467 F. Supp. 2d 431, 443 (D.N.J. 2006) ("A dispute is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the non-moving party.'") (quoting *Anderson*, 477 U.S. at 248). In addition, "[a] fact is 'material' only if it might affect the outcome of the suit under the applicable rule of law." *Id.*

C. Traditional Antitrust Analysis

Section 1 of the Sherman Act declares that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is . . . illegal." 15 U.S.C. § 1. It is well-settled, however, that this provision outlaws only unreasonable restraints of trade. *See State Oil v. Kahn,* 522 U.S. 3, 10 (1997). In order to determine whether an "unreasonable restraint" of trade has taken place, courts have traditionally used one of two different analyses: the *per se* rule and the rule of reason. *See State Oil Co.,* 522 U.S. at 10.

The *per se* analysis applies only under circumstances where courts have previously considered the type of conduct and found that its expected effects are overwhelmingly anticompetitive and have little prospect of yielding any pro-competitive benefit. *Id.* For a *per se* analysis to apply, the courts must have adequate judicial experience with the type of conduct at issue and must have found that it yields anticompetitive effects in the vast majority of cases (almost one-hundred percent of the time). *See* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition,* 39 U.S.F. L. Rev. 11, 19-20. Under the *per se* approach, a court can condemn the action as a *per se* illegal restraint on trade "without elaborate inquiry into the defendant's market power, the actual anticompetitive effects of the restraint in a particular case, or the rationales offered for it." *Id.* at 20. The *per se* analysis applies to only a few types of conduct, including "naked" exit payments (those payments made solely to keep a competitor out of the market), market-division agreements, and price fixing. *Id.* at 20-21.

In most cases, where the conduct is not so clearly anticompetitive, courts use the rule of reason analysis. Further, courts have begun to realize that categorization of conduct often is not clear cut, *id.* at 20-21, and that "[t]here is always something of a sliding scale in appraising reasonableness." *Cal. Dental Ass'n v. Fed. Trade Comm'n,* 526 U.S. 756, 780 (1999). In the

rule of reason analysis, "'the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'" *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 201 n.13 (2d Cir. 2006), *cert. denied sub. nom., Joblove v. Barr Labs, Inc.*, 127 S.Ct. 3001 (2007) *("Tamoxifen II")* (quoting *State Oil Co.*, 522 U.S. at 10).[18]

Courts have divided the rule of reason analysis into three parts, which involve burden-shifting between the two parties. First, the plaintiff must show that the conduct has produced adverse, anti-competitive effects within the relevant market. *U.S. v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). *See also Tamoxifen II,* 466 F.3d at 201 n. 13. If the plaintiff is able to prove this effect, then the burden shifts to the defendant, who must attempt to prove that the conduct "promotes a sufficiently pro-competitive objective." *Id.* at 669. If the defendant meets this standard, the burden then shifts back to the plaintiff to prove that the restraint is not reasonably necessary to achieve the pro-competitive objective. *Id.*

In addition to the *per se* and rule of reason standards, a third type of analysis has evolved: the "quick look" or "truncated rule of reason." *See Fed. Trade Comm'n v. Ind. Fed'n of Dentists,* 476 U.S. 447, 459 (1986). The truncated rule of reason analysis permits the plaintiff to shift the burden to the defendant more quickly, once the plaintiff has shown that the defendant has engaged in conduct similar to those practices falling into the per se category, e.g., restraints on price, output or customers. *Id.* The plaintiff need not establish the relevant market or the defendant's market power, but the defendant has the opportunity to demonstrate pro-competitive justifications and efficiencies. *Id.*

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[18] The opinion in *Tamoxifen II* amended and superseded *In re Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370 (2d Cir. 2005) (*"Tamoxifen I"*). *Tamoxifen II* predominantly made changes and corrections to the citations in the

D. Analyses Applied By Other Courts to "Reverse Payment" Settlements

To date, only a few courts have considered the issue of what analytical framework should be applied to antitrust claims involving reverse payment settlements of patent litigation by pioneer and generic drug companies. Although one Circuit Court has applied a *per se* analysis, the other courts that have considered this issue have adopted approaches that focus on the exclusionary scope of the patent at issue. The reasoning of these cases is summarized below.

1. The Sixth Circuit's *Per Se* Analysis

The Sixth Circuit was the first federal appellate court to consider the legality of a settlement involving a reverse payment. *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *cert. denied,* 543 U.S. 939 (2004). In that case, the brand name drug maker, Hochst Marion Roussel ("HMR"), manufactured and sold the drug Cardizem CD. *Id.* at 901. HMR's original patent for the active ingredient of Cardizem CD expired in late 1992. *Id.* In September 1995, a generic manufacturer, Andrx, Inc., filed an ANDA and submitted a Paragraph IV certification, stating that its drug did not infringe the patents covering Cardizem. *Id.* at 902. As the first ANDA filer, Andrx was eligible for the 180-day exclusivity period. *Id.* In November 1995, HMR received a new patent for Cardizem CD's "dissolution profile." *Id.* In January 1996, HMR sued Andrx for patent infringement, thus triggering the 30-month stay of FDA approval of Andrx's ANDA. *Id.* In September 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved upon the expiration of the stay or a court ruling of non-infringement. *Id.*

Shortly after the FDA granted tentative approval, HMR and Andrx entered into the agreement that was at issue in the case. *Id.* Among its terms, the agreement provided that Andrx would not market a generic version of Cardizem CD until the earliest of: (1) a final,

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Tamoxifen I opinion, but did not modify the court's analysis or holding.

unappealable determination in favor of Andrx in the infringement case; (2) HMR and Andrx entering into a license agreement; or (3) HMR entering into a license agreement with a third party. *Id.* Andrx further agreed not to "relinquish or otherwise compromise" its right to the 180-day exclusivity period. *Id.* In exchange, HMR agreed to make quarterly payments of $10 million to Andrx beginning on the date its ANDA received final FDA approval. *Id.*

On July 9, 1998, the FDA approved Andrx's ANDA, and HMR began making quarterly payments to Andrx. *Id.* at 903. Only in June 1999, after the FDA approved a reformulated generic version submitted by Andrx, did the two companies terminate their agreement and enter into a final settlement of the patent infringement suit. *Id.* At the time of the settlement, HMR made a further payment of $50.7 million to Andrx, bringing the total payments to more than $89 million. *Id.* On June 23, 1999, Andrx began marketing its generic product, triggering its 180-day exclusivity period. *Id.*

The court found that the parties' agreement was "at its core, a horizontal agreement to eliminate competition" and, thus, "a classic example of a *per se* illegal restraint of trade." *Id.* at 908. In finding the agreement *per se* illegal, the Sixth Circuit appeared particularly troubled by the fact that HMR's agreement with Andrx effectively used the 180-day exclusivity period to delay the entry of other generic competitors. In this regard, the court noted:

> By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter the market until the expiration of Andrx's 180 period of exclusivity, *which Andrx had agreed not to relinquish or transfer*.

Id. at 907 (emphasis added).

2. The Eleventh Circuit Approach in *Valley Drug* and *Schering v. FTC*

(a) *Valley Drug*

Three months after the *Cardizem* decision, the Eleventh Circuit reached a different result in the case of *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003). *Valley Drug* involved separate settlement agreements between Abbott Laboratories and two generic competitors, Geneva Pharmaceuticals and Zenith Goldine Pharmaceuticals, which had filed ANDAs challenging Abbot's patents relating to Hytrin, a brand name hypertension drug marketed by Abbott since 1987.[19] *Valley Drug*, 344 F.3d at 1298. Abbott filed suit against Geneva alleging infringement of its '207 Patent. *Id.* at 1299. In the suit, Geneva admitted infringement but asserted that Abbott's patent was invalid. *Id.* Zenith filed its own lawsuit against Abbott seeking delisting of the '207 Patent and another Abbott patent (from the Orange Book), and requesting a declaratory judgment that its generic product did not infringe the two patents. *Id.* Abbott asserted counterclaims for infringement against Zenith. *Id.*

Abbott entered into an agreement with Zenith on March 31, 1998 and with Geneva one day later. The Zenith Agreement included the following terms: (1) both parties dropped their lawsuit claims; (2) Zenith acknowledged the validity of Abbott's patents and admitted that any generic terazosin product it might market would infringe those patents; (3) Abbott agreed to make quarterly payments of $6 million dollars to Zenith until March 1, 2000 or the termination of the agreement; (4) Zenith agreed not to market any product containing terasozin hydrochloride until Abbott's '207 patent expired on February 17, 2000; and (4) Zenith agreed not to transfer any of its ANDA rights, including the 180-day exclusivity period it earned as the first ANDA filer. *Id.* at 1300.

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[19] Abbott had multiple patents relating to terazosin hydrochloride, the active ingredient in Hytrin. *Id.* The patents covered various forms of the terazosin hydrochloride compound and methods for using it. *Id.*

Similarly, under the terms of the Geneva Agreement: (1) Abbott agreed to pay Geneva $4.5 million per month, until another manufacturer brought a terazosin product to market, or Abbott won the '207 patent infringement suit; (2) Geneva agreed not to market any terazosin product until a second patent expired in February 2000 or until it obtained a court judgment of non-infringement or invalidity in the '207 patent infringement suit; (3) Geneva agreed not to transfer its rights under the ANDA, including its 180-day exclusivity period; and (4) Geneva agreed to challenge any subsequent ANDA filer's attempt to enforce the "successful defense" requirement. *Id.* On September 1, 1998, the district court hearing Abbott's infringement suit against Geneva declared the '207 Patent invalid. *Id.* at 1301 (citing *Abbott Labs. v. Geneva Pharms., Inc.*, 1998 WL 566884 (N.D. Ill. Sept. 1, 1998). That decision was affirmed by the Federal Circuit, and Abbott's petition for certiorari was denied. *Id.* (citing 182 F.3d 1315 (Fed. Cir. 1999) and 528 U.S. 1078).

In the subsequent private antitrust action, the Eleventh Circuit reversed the district court's decision granting summary judgment against the defendants.[20] *Valley Drug,* 344 F.3d at 1295. The Eleventh Circuit concluded that the district court misapplied the law when it found the agreements to be *per se* antitrust violations. *Id.* at 1295. The court reasoned that the "exclusionary potential of the ['207] patent" shielded the agreements' effects from *per se* antitrust evaluation. *Id.* at 1311. Thus, because the '207 patent would not expire until 2014, the effect of the agreements on competition was "no broader than the potential exclusionary effect of

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[20] On remand, the district court still applied a *per se* analysis and found the agreements at issue in *Valley Drug* to be *per se* illegal. *See In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 1279 (S.D. Fla. 2005). However, in its subsequent decision in *Schering,* the Eleventh Circuit found the agreements in *Valley Drug* to be "wholly different" from the Upsher and ESI Agreements. *Schering,* 402 F.3d at 1066, n.14. The court noted that the "critical difference" is that the agreements in *Valley Drug* did not involve final settlements of the patent litigation, and did not permit the generic company to market its product before patent expiration. *Id.*

the '207 patent, and was actually narrower to the extent [they] permitted Zenith [and Geneva] to market [their] drug[s] before the '207 patent expired." *Id.* at 1305.

While the court noted that the agreements resembled a horizontal market allocation, it recognized that the patent rights held by Abbott changed the evaluation. *Id.* at 1304. The court emphasized that the patent grant involves the right to exclude, which can lead to lawful agreements allocating the market geographically or by customer type. *Id.* at 1304. The court concluded that the district court erred when it focused on market allocation without considering the lawful exclusionary rights granted to Abbott under the '207 Patent. *Id.* at 1305.

The court further concluded that it was inappropriate to analyze the agreements under a traditional rule of reason framework because "the anticompetitive effects of exclusion cannot be seriously debated." at 1311. Rather, the court reasoned, a threshold analysis of the exclusionary scope of the patent must precede any specific antitrust inquiry. *Id.* at 1312. If the terms of the agreements are found to have effects "beyond the exclusionary effects of Abbott's patent," they "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act." *Id.*

The court identified a number of factors influencing its reasoning. First, it emphasized the competing regimes of patent and antitrust law. *Id.* at 1305-06. Second, the fact that the '207 patent subsequently was found to be invalid was not dispositive. *Id.* at 1308. Rather, the court concluded, the "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Id.* at 1306 (citing *Polk Bros. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); *SCM Corp. v. Zerox Corp.*, 645 F.2d 1195, 1209 (2d Cir. 1981). Third, noting the "important role played by settlement in the enforcement of patent rights," the court rejected the notion that the mere existence or substantial size of a reverse payment" was

sufficient to trigger *per se* illegality, especially where the lack of any damages reduces the risk for the generic manufacturers in the infringement suit. *Id.* at 1309-10 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251-52 (E.D.N.Y. 2003) ("*Cipro I*") (discussing the asymmetries of litigation risk create by Hatch-Waxman and rejecting argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis)).

(b) *Schering v. FTC*

In Schering's appeal of the *Schering-FTC* decision, the Eleventh Circuit reversed the FTC and reaffirmed the reasoning first set forth in *Valley Drug*. *Schering*, 402 F.3d 1056. The court restated its view that "neither the rule of reason nor the *per se* analysis is appropriate in this context." *Id.* at 1065. Recognizing the tension between the antitrust and patent laws, the court observed:

> By their nature, patents create an environment of exclusion, and consequently, cripple competition. the anticompetitive effect is already present. "What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent law prevent antitrust liability for such exclusionary effects."

Schering (quoting *Valley Drug*, 344 F.3d at 1311, n.27). Clarifying the standard it adopted in *Valley Drug*, the court explained that "the proper analysis of antitrust liability requires an examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066.

Applying the foregoing analysis to the Upsher and ESI agreements, the Eleventh Circuit found them well within the scope of the patent and thus legal patent settlements.[21] *Id.* at 1076. In reaching this conclusion, the court emphasized the fact that the agreements permitted Upsher to enter the market more than five years before the '743 Patent expired, and ESI to enter the

market more than two years before the expiration of the patent. *Id.* at 1067-68. The court further noted that "there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were 'shams.'" *Id.* at 1068. The court rejected the FTC's contention that, absent the payments to Upsher and ESI, the parties could have "simply compromised" on earlier entry dates. Finding no evidence in the record to support this conclusion – which the court viewed as "somewhat myopic" – the court reasoned:

> It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. . . .
>
> By contrast, the Hatch-Waxman Amendments grant generic manufacturers standing to mount a challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003). Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. *Id.* Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.
>
> By entering into the settlement agreements, Schering realized the full potential of its infringement suit – a determination that the '743 patent was valid and that ESI and Upsher would not infringe in the future. Furthermore, although ESI and Uphser obtained less than they what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. *Id.*

Schering, 402 F.3d at 1074.

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[21] The Eleventh Circuit also rejected the FTC's conclusion that the Niacor license was not worth $60 million, but

Noting the "private and social benefits" of settlements in avoiding the "the inveterate and costly effects of litigation," the court reiterated its view that neither the presence of a reverse payment, nor its size, should "dictate the availability of a settlement remedy." *Id.* at 1075 (citing D. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits; Antitrust Rules and Economic Implications,* 54 Fla. L. Rev. 747, 760 (2002). The court further reasoned that "[a]n exception cannot lie, as the [FTC] might think, when the issue turns on validity (*Valley Drug*) as opposed to infringement (the Schering agreements)." *Id.* at 1075-76.

3. The Second Circuit's *Tamoxifen* Decision

In *Tamoxifen II,* the Second Circuit considered a "reverse payment" settlement between the pioneer drug company, Zenica,[22] and generic manufacturer Barr Laboratories.[23] *Tamoxifen II,* 466 F.3d at 190. Zeneca held the patent rights to and manufactured tamoxifen citrate, a leading breast cancer drug. *Id.* at 193. Barr filed an ANDA for a generic version of tamoxifen, which it amended in 1987 to include a Paragraph IV certification. *Id.* After Zeneca timely sued Barr and Barr's raw material supplier for patent infringement, the district court declared Zeneca's patent invalid based on its conclusion that Zeneca deliberately withheld information from the PTO. *Id.* Zeneca appealed the invalidity decision, and in 1993, while the appeal was pending, the parties entered into a settlement agreement. *Id.*

Under the agreement's principal terms: (1) Barr agreed not to market its generic version of tamoxifen until Zeneca's patent expired in 2002 and thus amended its ANDA to a Paragraph III certification; (2) Barr received a non-exclusive license to sell tamoxifen tablets manufactured

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was a payment to keep Upsher off the market, and stated that the FTC's conclusion was "not supported by law or logic." *Id.* at 1070.

[22] Zeneca refers collectively to Imperial Chemical Industries, PLC ("ICI") and its former subsidiaries, Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and Astra Zeneca PLC, which succeeded to ICI's rights to the patent at issue. *Tamoxifen II,* 466 F.3d at 190, 193.

[23] The case was before the Second Circuit on plaintiffs' appeal of the district court's dismissal of their antitrust claims pursuant to Fed. R. Civ. P. 129b)(6). *Id.*

by Zeneca under Barr's own label; (3) Zeneca agreed to pay Barr $21 million plus an additional $45 million over ten years to Barr's raw material supplier; and (4) the parties agreed that if Zeneca's patent were subsequently declared invalid or unenforceable in a final, unappealable judgment, Barr would be allowed to revert to a Paragraph IV certification. *Id.* 193-94. In addition, pursuant to the settlement, the parties jointly moved for *vacatur* of the district court's patent invalidity judgment, which motion was granted by the Federal Circuit. *Id.* at 194.

The validity of Zeneca's patent was subsequently challenged by three other ANDA filers, all of whom were unsuccessful in their attempts to rely on the vacated invalidity judgment. *Id.* at 195. In each case, the court upheld the validity of Barr's patent. *Id.* In the meantime, the "successful defense" rule was invalidated, and Barr became eligible for the 180-day exclusivity period, which would only be triggered by Barr marketing its own generic version of tamoxifen. *Id.* at 195-96. In March 1999, the FDA confirmed Barr's entitlement to the exclusivity period. *Id.* at 196.

The private antitrust plaintiffs alleged that the settlement agreement unlawfully: (1) enabled Zeneca and Barr to "resuscitate" a patent that had been held invalid and unenforceable; (2) perpetuated Zeneca's monopolization of the tamoxifen market and allowed Zeneca and Barr to share the monopoly profits; and (3) maintained artificially high prices for tamoxifen and prevented competition from other generic manufacturers. *Id.* at 196-97.

The Second Circuit affirmed the district court's dismissal of the antitrust complaint and upheld the legality of the settlement. *Id.* at 197-99. In reaching its decision, the court noted the tension between the antitrust laws and an innovator's right under patent law to exclude competition. *Id.* at 201. The court further emphasized "our longstanding adherence to the

principle that 'courts are bound to encourage' the settlement of litigation." *Id.* at 202 (citing *Gambale v. Deutsche Bank AG,* 377 F.3d 133, 143 (2d Cir. 2004). The court observed:

> It is well settled that '[w]here there are legitimately conflicting [patent] claims . . ., a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition. . . .
>
> Rules severely restricting patent settlements might also be contrary to the goals of the patent law because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.

Id. (quoting *Standard Oil Co. v. United States,* 283 U.S. 163, 171 (1931) (other citations omitted).

The court also declined to find the settlements unlawful based on plaintiffs' contention that the Federal Circuit would have affirmed the invalidity of Zeneca's patent. *Id.* at 203-05. "We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal." *Id.* at 203 (citing, *inter alia, Asahi Glass Co. v. Pentech Pharms., Inc.,* 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("No one can be *certain* that he will prevail in a patent suit."); *In re Ciprofloxacin Hydrochloride Anititrust Litig.,* 261 F. Supp. 2d 188, 200-01 (E.D.N.Y. 2003) (noting that courts should not speculate about the outcome of litigation); *Valley Drug,* 344 F.3d at 1306 ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.")).

Citing with approval the reasoning of the courts in *Cipro I, Valley Drug, Schering,* and *Asahi Glass,* the court further court held that the mere existence of a reverse payment, especially in the context of the Hatch-Waxman Act, is not enough to trigger *per se* unlawfulness. *Id.* at 205-6 (citing *Valley Drug,* 344 F.3d at 1309; *Asahi Glass,* 289 F. Supp. 2d at 994; *Cipro I,* 261 F. Supp. 2d at 252; *Schering,* 402 F.3d at 1074). While the court acknowledged that reverse

payments may seem "suspicious," it reasoned that this "suspicion abates upon reflection." *Id.* at 208. Rather, the court held, "*so long as the patent litigation is neither a sham nor otherwise baseless*, the patent holder is seeking to arrive at a settlement in order to protect that to which it presumably entitled: a lawful monopoly." *Id.* at 208-09 (emphasis added). In this sense, the settlement did not exceed the scope of the patent. *Id.* at 209 n.22.

The court also noted its general agreement with the Eleventh Circuit regarding the importance of analyzing the scope of the patent, and concluded: "Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly." *Id.* at 212. The court agreed that "'[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.'" *Id.* at 213 (quoting *In re Ciprofloxacin Hydrocholoride Antitrust Litig.*, 363 F. Supp. 2d 514, 535 (E.D.N.Y. 2005) ("*Cipro II*").

4. *In re Cipro*

On October 15, 2008, the Federal Circuit Court of Appeals affirmed the district court's decision in *Cipro II* granting summary judgment in favor of the defendants. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, (Fed. Cir. 2008) ("*Cipro III*"). The facts of the *Cipro* case are generally similar to those of the cases discussed above. Bayer held a patent for the active ingredient in the branded drug Cipro, which patent had an expiration date of December 9, 2003. *Id.* at 1327-28. In 1991, Barr Labs, Inc. filed an ANDA with a paragraph IV certification for a generic version of Cipro. *Id.* at 1328. Thereafter, Bayer sued Barr for patent infringement. *Id.*

Shortly before trial, Bayer entered into settlements with Barr and other generic manufacturers. Pursuant to Bayer's settlement with Barr, Barr agreed to convert its paragraph IV ANDA to a paragraph III ANDA, thus certifying that it would not market its generic version of Cipro until after Bayer's patent expired. *Id.* at 1328-29. In exchange, Bayer agreed to make a settlement payment of $49.1 million to Barr. *Id.* at 1329. Under a separate "Cipro Supply Agreement," Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments to Barr until December 31, 2003. *Id.* Barr, in turn, agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. *Id.* Beginning at least six months before the expiration of Bayer's patent, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. *Id.* Bayer and Barr then entered into a consent judgment under which Barr affirmed the validity and enforceability of Bayer's patent and admitted infringement. *Id.*

In the subsequent antitrust action brought by indirect and direct purchasers, the district court granted summary judgment in favor of defendants. *Id.* at 1329 (citing *Cipro II,* 363 F. Supp. 2d at 548). Using a rule of reason analysis, the district court first determined that the relevant market was ciprofloxacin and that Bayer had market power within that market. *Id.* at 1330. The court then concluded that "any adverse effects on competition stemming from the Agreements were within the exclusionary zone of [Bayer's patent], and hence could not be redressed by antitrust law." *Id.* Having determined that there was no evidence that the Agreements "created a bottleneck on challenges to [Bayer's patent] or otherwise restrained competition beyond the scope of the patent," the district court concluded that the plaintiffs had failed to show that the Agreements had an anticompetitive effect beyond that authorized by the patent. *Id.*

Affirming the district court, the Federal Circuit distinguished the Sixth Circuit's decision in *Cardizem* and stated:

> We find . . . the district court's analysis to be sound. . . .[T]he district court applied a rule of reason analysis in assessing the lawfulness of the Agreements. In that analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent. The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch-Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a per se violation of the antitrust laws in *In re Cardizem,* the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. *In re Cardizem,* 332 F.3d at 907. Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. *Id.* at 908 n. 13. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent. [citation omitted] To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.

Id. at 1335.

Citing with approval the approaches adopted by the Eleventh and Second Circuits, the Federal Circuit concluded:

> [I]n cases such as this, wherein all anticompetitive effects of the settlement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.

Id. at 1336 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175-77 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is and exception to the general rule against monopolies). The court further noted its agreement with the Second and Eleventh Circuits that "in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.*

E. Framework Applicable to the Upsher and ESI Settlements

Having considered the analyses of the cases summarized above, I first conclude that the Upsher and ESI settlements were not *per se* unlawful. DP Plaintiffs' arguments that a *per se* approach is consistent with "traditional antitrust principles" and the legislative purpose of the Hatch-Waxman Act ignore the important purpose underlying the exclusionary rights granted by patent law. *See Tamoxifen,* 429 F.3d at 385; *Cipro III,* 544 F.3d at 1333. Moreover, with the sole exception of the *Cardizem* case, all of the courts that have considered so-called "reverse payment" settlements, as well as the FTC, have declined to apply a *per se* analysis. *See Valley Drug,* 344 F.3d at 1304; *Schering,* 402 F.3d at 1065; *Tamoxifen II,* 466 F.3d at 206; *Schering-FTC,* 2003 FTC LEXIS 187, at * 13, 22-27. *But see In re Cardizem,* 332 F.3d at 908. To the extent that the *Cardizem* court reached a contrary conclusion, the facts of that case are distinguishable.

Unlike the interim settlement in *Cardizem,* Schering's settlements in this case finally resolved its litigation with Upsher and ESI. Moreover, the settlement agreements in this case permitted the Upsher and ESI generic products to enter the market five years and almost three years, respectively, before the expiration of Schering's '743 Patent. Finally, the agreements in this case did not manipulate the 180-day exclusivity period to create a "bottleneck" precluding

the entry of other generic drugs. Upsher's settlement with Schering did not preclude Upsher from transferring or relinquishing the 180-day exclusivity and, because the "successful defense" requirement was in place at the time of the settlement, Upsher arguably was not entitled to the exclusivity period.

I further decline to adopt the "FTC/Hovenkamp" framework proposed by DP Plaintiffs, and note that Plaintiffs have not cited – nor am I aware of – any case that has applied this legal framework. The standard articulated by the FTC treats settlements involving reverse payments as presumptively anticompetitive, but purports to allow rebuttal of that presumption with a showing the pro-competitive effect of the settlement. *Schering-FTC*, 2003 FTC LEXIS, at *57-58. However, the order entered by the FTC prohibited settlements in which the generic company "receives anything of value," with an exception for payments, limited to $2 million, linked to litigation costs. *Id.* at *176. Similarly, the framework suggested by Professor Hovenkamp applies a rebuttable presumption of illegality, which the infringement plaintiff can rebut by showing both "(1) that the *ex ante* likelihood of prevailing in the infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of the litigation and collateral costs attending the lawsuit." *See* Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2003) (emphasis added).

Similar to a *per se* analysis, the FTC/Hovenkamp framework effectively discounts the fact that Schering's '743 Patent gave it the right to exclude infringing competitors. Moreover, it essentially requires a presumption that if the patent holder pays money to the generic company, the patent at issue must be either invalid or not infringed. In my view, the weight of authority counsels against adopting such a presumption. *See, e.g., Schering,* 402 F.3d at 1066 (noting

presumption of patent validity); *Tamoxifen,* 466 F.3d at 208-09; *Cipro II,* 363 F. Supp. 2d at 534-35 (declining to infer invalidity based on reverse payment).

I recognize that in this case, the key disputed issues in the patent case involved infringement, rather than validity. In this regard, DP Plaintiffs note that although patents are presumptively valid by statute; *see* 35 U.S.C. § 282), there is no corresponding presumption of infringement. *See* Framework Mem., p. 11. Thus, according the DP Plaintiffs, the probabilistic nature of patents is particularly relevant. *Id.* DP Plaintiffs further contend that Schering's payments to Upsher and ESI are *prima facie* evidence that the parties expected the litigation to result in more competition than was provided for under the settlement agreements. Plaintiffs' arguments are unpersuasive. Although there is no presumption of infringement, neither is there a statutory presumption that Schering's patent was not infringed. *See Schering-FTC,* 2003 FTC LEXIS 187, at * 61 ("We cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent any more than we can assume that Upsher had the right to enter earlier.") (emphasis added).

Accordingly, I decline to discount the exclusionary power of Schering's patent based on the *possibility* that it was not infringed by the Upsher and ESI products. *See Cipro II,* 363 F. Supp. 2d at 514 and n. 19 (rejecting argument that exclusionary power of the patent should be discounted by the probability of an invalidity finding, and noting the applicability of its analysis to cases in which infringement is the dominant issue); *Tamoxifen,* 466 F.3d at 211-12 (citing *Cipro II,* supra); *Asahi Glass,* 289 F. Supp. 2d at 992-93 ("It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit."). In addition, I conclude that it is inappropriate to conduct an *ex post* inquiry into

infringement issues that were resolved by the parties' settlement. As the *Cipro II* court observed regarding issues of patent validity, "[s]uch an inquiry would undermine any certainty for patent litigants seeking to settle their disputes." *Cipro II,* 363 F. Supp. 2d at 530. *See also Schering,* 402 F.3d at 1072-73 (noting public policy favoring settlement of patent disputes); *Schering-FTC,* 2003 FTC LEXIS 187, at * 60 (expressing concern that "a mandated inquiry into [the merits of the patent case], as part of an antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation").

Finally, I reject DP Plaintiffs' suggestion that Judge Greenaway previously weighed and rejected the analytical framework that has now been adopted by the Second, Eleventh and Federal Circuits. In his Sept. 29, 2004 opinion, Judge Greenaway denied Defendants' 12(b)(6) motion to dismiss, finding, *inter alia,* that Plaintiffs' had adequately *alleged* anti-competitive conduct. As summarized by Judge Greenaway, Defendants had argued that:

> Plaintiffs fail to allege that Defendants engaged in anti-competitive behavior by entering into the settlement agreements. [Defendants] argue that Plaintiffs have not established anti-competitive behavior because the settlement agreements in question do not have an anti-competitive effect. Rather, the settlement agreements are pro-competitive because they allowed Upsher and ESI to enter the market years before Schering's K-Dur patent expired, and such agreements, as a matter of law, are not antitrust violations. By not alleging that the settlements do not reasonably reflect the objective merits of the patent suits, or that Upsher or ESI would have won the patent suit, Plaintiffs have not stated anti-competitive behavior, and thus have no claim.

In re K-Dur, 338 F. Supp. 2d 517, 530-31. Defendants further argued that the settlements (and the payments by Schering allegedly for delay) could not be anti-competitive because Schering had a valid patent and, thus, was entitled to exclude generic competitors until the patent expired. Thus, according to Defendants, absent an allegation of patent invalidity or non-infringement, the entry dates in the agreement are beyond attack. *Id.* at 531.

Contrary to DP Plaintiffs' suggestion, Judge Greenaway did not decide that the framework DP Plaintiffs' now propose (or any other framework) would apply beyond the pleading stage, *i.e.,* at dispositive motions or trial. On the contrary, in denying Defendants' Motion to Dismiss, he stated that "[i]n this Court's view Plaintiffs can sustain a claim of anti-competitive conduct simply by *alleging* facts which show that the outcome of the settlement agreements would have been more pro-competitive absent the cash payments from Schering to Upsher and ESI."[24] *Id.* at 532 (emphasis added). Moreover, Judge Greenaway noted the different standards that had been applied by the Sixth Circuit in *Cardizem* (reverse payments *per se* illegal) and the 11th Circuit in *Valley Drug* (rejecting *per se* approach), and expressly stated that he did not need to address whether Defendants' alleged conduct was *per se* illegal. *Id.* at 533. Further, although he noted that the FTC had found the Defendants' conduct unlawful and stated that the FTC's findings were "of some interest," he also stated that the FTC's findings were not binding, and he did not adopt the standard used by the FTC in its analysis.

Finally, Judge Greenaway's decision was issued in 1994, before the 11th Circuit's decision in *Schering* and before the decisions of the Second and Federal Circuits following the 11th Circuit approach. Thus, the Circuit Court case law regarding the appropriate analytical framework has developed significantly since Judge Greenaway decided Defendants' motion to dismiss in 2004.

In summary, I will not adopt the FTC/Hovenkamp framework, but, rather, will apply an analysis consistent with the approach that has been adopted by the Second, Eleventh and Federal

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[24] As Judge Greenaway noted, his opinion addressed a Rule 12(b)(6) motion to dismiss and was decided under the framework of that rule, which treats all of Plaintiffs' allegations as true and draws all inferences in Plaintiffs' favor. *Id.* at 527 (noting that Plaintiffs' alleged that but for the reverse payments, Upsher and ESI would have settled on different terms and entered the market sooner); 528 (noting the standard for 12(b)(6) and 12(c) motions); 529 (noting that there is no heightened pleading standard in antitrust cases); 533 (stating that Plaintiffs had sufficiently

Circuits. Under that framework, as long as the Upsher and ESI settlements restrained competition only within the scope of Schering's patent, or the underlying patent lawsuits were objectively baseless, Defendants are entitled to summary judgment on DP Plaintiffs' antitrust claims.

1. The Settlements Do Not Exceed the Exclusionary Scope of the '743 Patent

It is undisputed that the Schering's '743 Patent gave it the right to exclude infringing products until September 5, 2006. It is likewise undisputed that the Upsher Settlement permitted Upsher to market its generic product more than five years before the '743 Patent expired; and the ESI Settlement permitted ESI to market its generic product more than two years before the patent's expiration. Thus, with respect to the entry dates the parties agreed upon, the Upsher and ESI Agreements clearly were well within the exclusionary scope of the '743 Patent.

Having reviewed the Agreements and the record in this case, I further conclude that there is no evidence that any other aspects of the settlement exceeded the exclusionary scope of the '743 Patent.[25] In the Upsher Settlement, Upsher agreed not to market Klor-Con M20© or "any other sustained release microencapsulated potassium chloride tablet," prior to Sept. 1, 2001. DP Plaintiffs' contend that by virtue of the above-quoted language, the agreement precluded Upsher from marketing non-infringing products and exceeded the scope of the patent. I disagree. First, there is no evidence in the record that Upsher had developed or planned to develop and market "any other sustained release microencapsulated potassium chloride tablet." Absent evidence that any other such generic product existed or was contemplated by Upsher, there is simply no basis

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pled anti-competitive conduct and noting that, at pleading stage, court must consider defendants' pro-competitive justifications as unproven).

[25] Contrary to DP Plaintiffs' argument, Judge Greenaway did not decide that the terms of the Upsher and ESI Settlements exceeded the exclusionary scope of Schering's patent. Rather, he merely concluded that Plaintiffs had *alleged* that the settlement agreements exceeded the scope of the patent. *In re K-Dur,* 338 F. Supp. 2d at 532.

upon which to conclude that the terms of the Upsher Agreement exceeded the scope of the '743 Patent. Moreover, I note that in *Schering,* the Eleventh Circuit determined, on the record before it,[26] that the Upsher Agreement's restraint covering "sustained release microencapsulated potassium chloride tablet[s]" covered the "identical reach of the '743 patent" and was a lawful ancillary restraint. *Schering,* 402 F.3d at 1072 ("Ancillary restraints are generally permitted if they are 'reasonably necessary' toward the contract's objective of utility and efficiency.").

With respect to the ESI Agreement, DP Plaintiffs have not even argued that its terms exceed the exclusionary scope of the patent. Although the terms of the ESI Settlement included ESI's agreement not to conduct, sponsor or support an application for AB rating or equivalence study for a potassium chloride product with respect to K-Dur, ESI also expressly stated in the agreement that neither it nor any of its affiliates were developing, or planned or intended to develop any such product. Accordingly, as with the Upsher Settlement, there is no evidence that the ESI Agreement excluded any non-infringing products.

Finally, I reject DP Plaintiffs' argument in their '743 Motion that under the doctrine of prosecution history estoppel and the "All Elements Rule," the scope of the '743 patent cannot extend to exclude Upsher's generic product. The DPP's '743 Motion would require me not only to conduct a detailed inquiry into the merits of the patent case, but to decide the infringement issues that were resolved when Schering and Upsher settled. For the reasons discussed above regarding the analytical framework applicable to the Upsher and ESI Settlements, I decline to conduct such an inquiry. *See Cipro II,* 363 F. Supp. 2d at 524-30 (reviewing refusals of courts

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[26] The record in *Schering* included the ALJ's factual finding that the quoted language was included in the settlement so that "Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions," and because "Schering wanted to prevent Uphser-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement." *Schering-ALJ,* 2002 FTC LEXIS 40, at * 62-63 (¶ 158). The ALJ found that "no other restrictions on any of Uphser-Smith's other products were intended by the settlement agreements." *Id.*

and the FTC to undertake an after-the-fact inquiry into the merits of the patent issues in a settled case). To the extent that I consider the infringement issues raised by DP Plaintiffs, I do so only to determine whether Schering's patent lawsuits were objectively baseless.

2. Schering's Patent Infringement Lawsuits Against Upsher and ESI Were Not Objectively Baseless

Because I have concluded that the Upsher and ESI settlements did not exceed the exclusionary scope of the '743 Patent, DP Plaintiffs' antitrust claims fail unless they can show that Schering's patent litigation against Upsher and ESI was objectively baseless.[27] As set forth below, I conclude that DP Plaintiffs cannot satisfy the objectively baseless standard with respect to either of the patent lawsuits. In order to establish that Schering's patent lawsuits were objectively baseless, DP Plaintiffs must show that the lawsuits were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Professional Real Estate Investors, Inc. v. Columbia Pictures, Indus., Inc.*, 508 U.S. 49, 60 (1993) ("*PRE*"). If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is [not objectively baseless], and an antitrust claim premised on the sham exception must fail." *Id. See also Cheminor Drugs, Ltd. v.Ethyl Corp.*, 993 F. Supp. 271, 281 (D.N.J. 1998) (Greenaway, J.) (case must be shown to have "absolutely no objective merit"), *aff'd*, 168 F.3d 119 (3d Cir. 1999). Where there is no dispute over the "predicate facts" of the underlying lawsuit, the question of whether the suit was objectively baseless is a matter of law. *PRE,* 508 U.S. at 63-64. Predicate facts are the facts and circumstances that were available to the party that brought the underlying lawsuit. *PRE,* 508 U.S. at 63 (citing *Nelson v. Miller,* 607 P.2d 438, 444 (Kan. 1980). *See also In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 362 n. 7

[27] DP Plaintiffs do not contend that Schering's '743 Patent was procured by fraud on the PTO.

(D. Mass. 2004) (recognizing that probable cause is a question of law when the relevant predicate facts involve an unsettled condition of law).

The party seeking to establish that a lawsuit was objectively baseless must do so with clear and convincing evidence. *C.R. Bard, Inc. v. M3 Sys., Inc.,* 157 F.3d 1340, 1369 (Fed. Cir. 1998); *Handgards, Inc. v. Ethicon, Inc.,* 601 f.2d 986, 996 (9th Cir. 1979). "The U.S. Supreme Court has defined 'clear and convincing evidence' as evidence that places in the Court, as factfinder, an 'abiding conviction that the truth of its factual contentions are highly probable.'" *Bayer Schering Pharma AG v. Barr Laboratories, Inc.,* No. 05-cv-2308, 2008 U.S. Dist. LEXIS 15917, *50 (quoting *Colorado v. New Mexico,* 467 U.S. 310, 316 (1984) (internal quotation marks omitted)). *See also A.K. Stamping Co., Inc. v. Instrument Specialties Co., Inc.,* 106 F. Supp. 2d 627, 639 n. 13 (D.N.J. 2000) (Greenaway, J.) ("'Clear and convincing' falls between the 'reasonable doubt' standard governing criminal cases and the "preponderance of the evidence" standard typical of civil actions.").

(a) *The Upsher Case*

(i) *Prosecution History Estoppel*

DP Plaintiffs have argued that even if the objectively baseless standard applies, they have developed a record which establishes that it was virtually certain that Upsher would have won the patent case. DP Plaintiffs' principal argument is that Schering's primary infringement argument was legally baseless because, during prosecution of the '743 Patent, Schering amended its claims to require EC with a viscosity of "greater than 40 cp." Specifically, DP Plaintiffs note that during prosecution of the '743 patent -- in response to the examiner's rejection of its claims as obvious in light of the prior art -- Schering amended its claims to require an EC with a viscosity of "greater than 40 cp." Upsher's generic product, however, uses Ethocel 20, with a viscosity of 18-22 cp and, thus, did not literally infringe the '743 patent. Therefore, Schering

could only claim infringement under the "doctrine of equivalents." According to DP Plaintiffs, however, having surrendered its claim to a product using EC with a viscosity of less than 40 cp, Schering was barred by the doctrine of prosecution estoppel from claiming that Upsher's product using Ethocel 20 was equivalent to Schering's product claimed in the '743 patent.

Defendants dispute DPPs' contention that Schering's reliance on the doctrine of equivalents was objectively baseless. In the patent lawsuit, Key conceded that it was estopped from claiming equivalency as to EC described in the prior art '399 Patent, which had a viscosity of 9-11 cp. Key contended, however, that under the applicable law, it was not estopped from claiming equivalency as to EC with a range between the 11 cp disclosed in the prior art and the 40 cp literally claimed in the '743 Patent. Upsher moved for summary judgment contending that Key's amendment of the patent to recite a viscosity of "greater than 40 cp," estopped Key from claiming equivalence as to any product with a viscosity lower than 40 cp.

Defendants note that at the time Schering filed its lawsuit against Upsher, Federal Circuit law imposed a "flexible bar" under which a claim amendment did not necessarily surrender all range of equivalency regarding the subject matter literally given up by the amendment. *See Hughes Aircraft Co. v. United States,* 717 F.2d 1351, (Fed. Cir. 1983). However, shortly before the settlement, the Supreme Court issued a decision in the case of *Warner Jenkinson Co. v. Hilton Davis Chemical Co.,* 520 U.S. 17 (1997), which called into question the applicability and scope of the "flexible bar" rule. Thus, by the time of the settlement, the law regarding Schering's ability to rely on the doctrine of equivalents was unsettled. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki,* 234 F.3d 558, 574 (Fed. Cir. 2000) (noting inconsistency in rules as to the scope of prosecution history estoppel), *vacated on other grounds,* 535 U.S. 722 (2002). *See also In re Wellbutrin SR Antitrust Litig.,* 2006 U.S. Dist. LEXIS 9687, at *24 (E.D.

Pa. Mar. 9, 2006) (noting that during the 1980s and 1990s, there were two conflicting approaches to prosecution history estoppel, "the more prevalent of which was known as the flexible bar rule, according to which the doctrine of prosecution history estoppel extends only to the subject matter . . . relinquished during the prosecution"). In view of the unsettled state of the law regarding prosecution estoppel at the time of the Upsher litigation and settlement, I conclude that Schering's equivalence argument can not be deemed objectively baseless. To be sure, Schering might have lost the argument had the case proceeded to a decision on summary judgment or at trial. In this regard, I note that at the summary judgment argument, Judge Walls expressed doubt about Schering's infringement claim in light of the claim amendment. However, the test is not whether Schering might have lost the patent suit; it is whether the suit was so objectively baseless "that no reasonable litigant could realistically expect success on the merits." *PRE,* 508 U.S. at 60. I conclude as a matter of law that DP Plaintiffs cannot satisfy that test.

(ii) ***Other Equivalence and Inequitable Conduct Issues***

Finally, DP Plaintiffs argue that as a factual matter, Schering's argument in the patent case that the SMO in Upsher's product was equivalent to the HPC and PEG required by the '743 patent was objectively baseless. According to DP Plaintiffs, the facts show that: (1) Schering misrepresented the function of HPC and PEG as plasticizers; (2) Schering misrepresented the function of SMO as a plasticizer; and (3) Schering improperly ignored the principal function of HPC and PEG. DP Plaintiffs further argue that summary judgment should be denied so that a jury can consider the invalidity and unenforceability claims that Schering would have had to overcome to prevail on its infringement claim.

DP Plaintiffs' opposition to the Upsher Motion, and the parties' extensive recitations of the conflicting evidence in the patent case regarding these issues, foreclose any finding that Schering's lawsuit was objectively baseless. In particular, the issue of whether SMO was

equivalent to HPC was hotly disputed in the patent case, with both sides offering expert opinion in support of their positions. In addition, as Defendants note, Upsher argued in the patent case that multiple fact disputes precluded summary judgment in favor of Key on Upsher's inequitable conduct claim. Because it is clear that there were genuine factual and legal disputes regarding Schering's claims in the patent lawsuit, DP Plaintiffs cannot establish that those claims were objectively baseless.

(b) *The ESI Case*

DP Plaintiffs have not argued, nor identified any evidence, that Schering's patent litigation against ESI was objectively baseless. Moreover, it is undisputed that ESI had problems demonstrating the bioequivalence of its product to K-Dur and that the FDA had twice rejected ESI's bioequivalence studies. Additional undisputed evidence reflects that Schering believed ESI did not have a viable product and that Schering settled under some pressure from the presiding court. *See Schering-FTC,* 2003 FTC LEXIS 187, at *165 (acknowledging that "Schering was subject to intense, and perhaps unseemly, judicial pressure to settle the patent litigation, and [that] Schering may well have been concerned about its future litigation prospects if it resisted."). In sum, there is no evidence that Schering's lawsuit against ESI was objectively baseless, and, thus, Defendants are entitled to summary judgment on DP Plaintiffs' claims relating to the ESI Settlement.

IV. CONCLUSION

For the reasons set forth above, I conclude that Defendants' Motions for Summary Judgment as to DP Plaintiffs' claims relating to the Uphser and ESI Settlements should be granted. I further conclude that DP Plaintiffs' Motions for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments and as to the Exclusionary Scope of the '743 Patent should be denied.

As provided in the Order entered by Magistrate Judge Arleo in this matter, the Special Master's decision on any motion can be appealed to Judge Greenaway in the manner, and subject to the standards of review set forth in Rule 53 of the Federal Rules of Civil Procedure and applicable Local Rules.

ENTERED this
4th day of February, 2009

s/Stephen M. Orlofsky
STEPHEN M. ORLOFSKY
SPECIAL MASTER

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION	Civil Action No. 01-1652 (JAG) (Consolidated Cases)
This Document Relates To:	
All Direct Purchaser Actions	MDL Docket No. 1419

ORDER

The Special Master having considered: (1) the Motion of Defendants Schering-Plough Corporation and Upsher-Smith Laboratories, Inc. (collectively, "Defendants") for Summary Judgment as to All Claims Brought By Direct Purchaser Plaintiffs ("DPPs") Related to the Upsher Settlement; (2) Defendants' Motion for Summary Judgment as to All Claims Brought By DPPs Related to the ESI Settlement; (3) DPPs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments; and (4) DPPs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent, the briefs submitted by all parties in support of and in opposition to the Motions, and the oral argument of counsel, for the reasons set forth in the foregoing Report and Recommendation;

IT IS HEREBY ORDERED, this 4th day of February, 2009, that:

(1) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the Upsher Settlement is **GRANTED**;

(2) Defendants' Motion Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the ESI Settlement is **GRANTED**;

(3) DP Plaintiffs' Motion for Partial Summary Judgment as to the Applicable

Framework for Analysis of Exclusion Payments is **DENIED**; and

(4) DP Plaintiffs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent is **DENIED**.

ENTERED this
4th day of February, 2009

s/Stephen M. Orlofsky
STEPHEN M. ORLOFSKY
SPECIAL MASTER